

### **REMARKS/ARGUMENTS**

Claims 1-47 are currently pending. Claims 7, 14, 19, 33, 35, and 46-48 have been amended to correct spelling and grammatical errors. No new matter has been added.

The Examiner is thanked for his kind allowance of claims 14-18, 20-24.

Applicant appreciates the Examiner's indication that Claims 2, 6-12, 19, 28, 33-37, 39, 43, and 46-48 are allowable over the prior art if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, for the present, Applicant respectfully declines the opportunity to rewrite these claims in independent form but reserves the right to do so at a future time.

#### **Specification**

The Examiner is unclear what type of priority is being claimed. This application is intended as a child of parent 09/613,439 and is a continuation-in-part of parent 09/613,439. Applicant has amended the specification to clarify this and to state that application 09/613,439 is a divisional of U.S. patent application 09/071,284, which is now U.S. patent 6,162,192 (Cragg et al.).

#### **Claim Language**

##### **Claim Discrepancies**

The office action states that the punctuation between "distal" and "end" in claims 7, 14, and 33 is unclear. Claims 7, 14, and 33 have been amended to delete the punctuation.

##### **Claim Rejections – 35 U.S.C. §112**

Claims 7-12, 19, 35, 36 and 46-48 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that in Claim 7, the letter "b" is confusing and that in Claim 19, the number "6" has no clear meaning. Claims 7 and 19 have been amended to delete the typographical errors.

The Examiner stated that in Claim 35, the word "portions" has no clear meaning. Claim 35 has been amended to correct the typographical error and change "portions" to "portion".

The Examiner stated that in Claims 46-48, the scope of these claims is unclear. Claims 46-48 have been amended to correct the typographical errors and depend upon claim 45 or 46.

It is believed that the amendments place the claims in condition for allowance. Thus, it is respectfully requested that this rejection be withdrawn.

**First Claim Rejection – 35 U.S.C. §102**

Claims 1, 25, 38, and 44 are rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Cragg et al. (6,162,192). The Examiner cited 35 U.S.C. §102(e); however, the Examiner also stated that the rejection is made under 35 U.S.C. §102(b). Applicant is unclear about what section the rejection is made under, however, a rejection under either 35 U.S.C. §102(e) or (b) is respectfully traversed.

Under MPEP §706.02(b), a rejection under based on 35 U.S.C. 102(b) and (e) "can be overcome by: ... Perfecting priority under 35 U.S.C. 119(e) or 120 by amending the specification of the application to contain a specific reference to a prior application."

Thus, since the present application claims priority to and is a continuation-in-part of parent application 09/613,439, which is a divisional of Cragg et al., it is respectfully requested that this rejection be withdrawn.

**Second Claim Rejection – 35 U.S.C. §102**

Claims 38, 44, and 45 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Janzen (5,437,631). This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.<sup>1</sup>

The office action states:

“Janzen teaches advancing a control tip 32, 28, 22 through a subcutaneous tissue and into a blood vessel 12 through the puncture (figures 1 or 2) and advancing a tubular shaft 42 (figures 5 or 6, for example) over the control tip until a distal end of the tubular shaft engages the outer surface of the blood vessel (figure 5) and positioning a marker 47 along the tubular shaft against the epidermal outer shaft.”

Applicant respectfully disagrees. Upon a closer reading of Janzen, there are subtle but important differences between Janzen and the claimed invention.

**Claim 38**

Claim 38 provides for “advancing a control tip through subcutaneous tissue and into the blood vessel through the puncture.” The control tip includes “a hollow puncture control head 16 ... the head 16 includes a distal tapered portion 18, a proximal tapered portion 20, and a center portion 22 between the distal and proximal portions.”

(Specification, page 9, lines 16-20).

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<sup>1</sup> Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Janzen discloses a sheath dilator set "comprised of a sheath 32 and a dilator 26 that has a taper 28." (Col. 4, lines 49-51). Janzen teaches the use of a sheath and a dilator that has a taper. Janzen does not teach the use of a control tip as claimed in claim 38.

Furthermore, the Examiner cited "Janzen teaches advancing a control tip 32, 28, 22." The citations cited by the Examiner correspond to a sheath, a taper end, and a guidewire, respectively. Thus, it is unclear to Applicant what the Examiner is referencing and how each can be equated to a control tip.

Since Janzen does not teach each and every element as set forth in claim 38, it can not be said to anticipate the claimed invention. Thus, it is respectfully requested that this rejection be withdrawn.

Claim 44

Claim 44 provides for the following:

"A method of at least partially controlling blood flow through a puncture site in a blood vessel wall, comprising the steps of:

inserting a control tip through the vessel wall at the puncture site and at least partially into the blood vessel; and

positioning a pledget adjacent to an outer surface of the blood vessel wall at the puncture site with the control tip still at least part in the vessel puncture site."

As stated above, Janzen discloses a sheath dilator set "comprised of a sheath 32 and a dilator 26 that has a taper 28." (Col. 4, lines 49-51). Janzen teaches the use of a sheath and dilator and not a control tip as claimed in claim 44.

Furthermore, Janzen discloses "when the procedure is completed, dilator 36 can be removed, a preloaded sleeve 45 like that depicted in FIG. 4 can be used to insert hemostatic material ..." (Col. 5, lines 30-33). Thus, Janzen does not teach positioning the pledget "with the control tip still at least part in the vessel puncture site" as provided in claim 44.

Since Janzen does not teach each and every element as set forth in claim 44, it can not be said to anticipate the claimed invention. Thus, it is respectfully requested that this rejection be withdrawn.

Claim 45

Claim 45 provides for:

"A method for positioning a pledget adjacent to the exterior surface of a blood vessel puncture site, comprising:  
    holding a pusher stationary relative to a delivery cannula;  
    retracting a delivery cannula proximally relative to said pusher to expose a distal end of the pledget; and  
    advancing the pusher distally relative to the delivery cannula, whereby the entire pledget is simultaneously exposed and compressed against the exterior surface of the blood vessel puncture site."

The office action did not provide any citations to and Janzen does not teach "holding a pusher stationary relative to a delivery cannula, retracting a delivery cannula proximally relative to said pusher to expose a distal end of the pledget, and advancing the pusher distally relative to the delivery cannula" as claimed in claim 45.

Thus, since Janzen does not teach each and every element as set forth in claim 45, it can not be said to anticipate the claimed invention. Thus, it is respectfully requested that this rejection be withdrawn.

**Remaining Dependent Claims**

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

In view of the foregoing, among others, it is respectfully asserted that the claims are now in condition for allowance.

**Summary**

It is believed that this Amendment places the above-identified patent application into condition for allowance. Early favorable consideration of this Amendment is earnestly solicited.

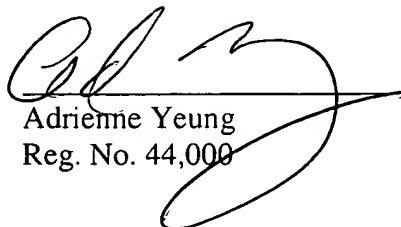
If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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